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June 29, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

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## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statements:

Herbal Fatigue Fighter

- Supports Cellular Energy Supports Endurance and Resistance to Stress
- Supplements Your Body's Own Defenses Against Fatigue

Your Life@ Fatiguex™ is a unique complex of vitamins, herbs and minerals that helps fight fatigue.

The main component of Your Life@ Fatiguex™ is Rhodiola Rosea. Similar to ginseng, Rhodiola is an adaptogen, which can help the body fight fatigue by increasing endurance and resistance to stress.

Fatiguex™ helps you combat fatigue by supplementing your system's natural defenses with these important vitamins and minerals.

Vitamins B1, B2, and 812, niacin, and coenzyme Q10 are necessary cofactors in the release of energy from food and energy metabolism.

**L-Carnitine** is an amino acid that transports fat into the cell's furnace (mitochondria), where it is burned to produce energy.

on the following product:

YourLife® Fatiguex™

Very truly yours,

Leiner Health Products

Hany Farag, Director of Regulatory Affairs

c: William Cochran, Manager of Regulatory Affairs

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